2320 NW 66TH COURT
GAINESVILLE, FL 32653
352-377-1140
FAX 352-378-2617

NOV 1 3 2003

K032964

Exactech®
Alumina Femoral Heads
12/14 M-Series Neck Segments

510(k) Summary of Safety and Effectiveness
Special 510(k)

Sponsor: **Exactech® Inc.**
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: (352) - 377 - 1140
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FDA Establishment Number 1038671

Contact: **Gary J. Miller**
Exec. V.P. of Research & Development

Date: **October 22, 2003**

Exactech®
Alumina Femoral Heads
12/14 M-Series Neck Segments

510(k) Summary of Safety and Effectiveness
Special 510(k)

Trade / Proprietary Name:	Exactech
Model Name:	12/14 Alumina Femoral Head
Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Product Code:	LZO
C.F.R. Section:	not specified
Device Class:	II
Classification Panel:	Orthopedic

Trade / Proprietary Name:	Exactech AcuMatch
Model Name:	M-Series 12/14 Neck Segment
Name:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous, Uncemented
Product Code:	LPH
C.F.R. Section:	888.3358

Legally Marketed Devices for Substantial Equivalence Comparison:

Exactech Zirconia Ceramic Femoral Head	#K914574 #K931617
Exactech AcuMatch M-Series Femoral Stems (Neck Segments)	#K010120

Exactech®
Alumina Femoral Heads
12/14 M-Series Neck Segments

510(k) Summary of Safety and Effectiveness
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Device Description:

INDICATIONS
All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

AcuMatch M-Series 12/14 Neck Segments and Exactech 12/14 Alumina Femoral Heads are intended to be used in press-fit and cemented applications.

CONTRAINDICATIONS
Exactech Hip Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system. The L-Series unipolar and bipolar endoprostheses are also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.

Exactech 12/14 Alumina Femoral Heads
This Special 510(k) application supports design changes to the proposed BIOLOX®*forte* 12/14 Ceramic Femoral Heads relative to Exactech's predicate Zirconia Ceramic Femoral Heads (#K914574, #K931617). The modifications include a change in the ceramic material composition from zirconia to alumina and a change in the taper geometry from a proprietary 11/13 design to a European 12/14 design.

The proposed Ceramic Femoral Heads are composed of CeramTec BIOLOX®*forte* alumina material and have a European 12/14 bore design. The material properties of BIOLOX®*forte* are described in FDA Master Files MAF-197, MAF-746, and MAF-747.

Exactech®
Alumina Femoral Heads
12/14 M-Series Neck Segments

510(k) Summary of Safety and Effectiveness
Special 510(k)

AcuMatch M-Series 12/14 Neck Segments
This Special 510(k) application supports modification of the AcuMatch M-Series neck segments (#K993736, #K010120). Modifications were made to the femoral stem cone design, neck geometry and through-hole diameter. The material composition, surface finish, neck angle, neck length and metaphyseal taper connection are unchanged.

Conclusion:
Testing and engineering evaluations were conducted to verify that the performance of the new 12/14 alumina heads and the 12/14 neck segments would be adequate for anticipated *in vivo* loading. Based on successful results we conclude that the proposed devices are substantially equivalent Exactech's predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Ms. Lisa Simpson
Senior Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K032964
Trade/Device Name: Exactech 12/14 Alumina Femoral Head,
Exactech AcuMatch M-Series 12/14 Neck Segment
Regulation Number: 21 CFR 888.3358, 21 CFR 888.3353
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO
Dated: October 22, 2003
Received: October 23, 2003

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(#4)

Exactech®, Inc.

Exactech 12/14 Alumina Femoral Head
Exactech AcuMatch M-Series 12/14 Neck Segment

Indications for Use

510(k) Number: K032964

INDICATIONS

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Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over the Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032964